

REMARKS/ARGUMENTS

Claims 1, 19, 21, 24-27, and 29-32, and 34-36 are pending. Claims 1, 19, 21, 24-27, and 29, 31-32, and 34-36 are rejected, and claims 30 and 36 are objected to. In this Amendment, claim 30 is amended. Reconsideration is respectfully requested.

First Claim Objection

Presently pending claim 30 was objected to under 37 C.F.R. §1.75(c) as allegedly not further limiting the subject matter of the previous claim. This objection is traversed.

Amended claim 30 indicates that the colloid further comprises a polysaccharide. Withdrawal of this rejection is respectfully requested.

Because claim 30 was not substantively rejected, it is believed that claim 30 is now in condition for allowance.

It is improper to conclude that claim 1 is limited to an aqueous colloid being a protein. Instead, presently pending claim 1 indicates that the colloid comprises a protein. With regard to patent claim construction, there is a difference between a colloid that is a protein, and a colloid that comprises a protein.

To be clear, the term "comprise" is open language. It is commonly accepted that some form of the word "comprise" is used in most claims. Such terms are inclusive or open-ended and do not exclude additional, unrecited elements. Terms such as "comprise" are used in claim language to mean that the named elements are required, but other elements may be added and still form a construct within the scope of the claim. When used in patent claims, these open terms create a presumption that the recited elements are only part of the claim.

For example, when claim 1 indicates that the colloid comprises a protein, this means that the claim requires a protein, but does not exclude other unidentified elements. There is no requirement that Applicant specifically name all other elements that may be encompassed by the open language of the claim. In fact, open language terms permit unnamed elements to be encompassed within the scope of the claim. As expressly discussed in MPEP 2163(II)(A)(I), such terms leave the claim open for the inclusion of unspecified ingredients even in major amounts.

In sum, it is noted that open language terms such as “comprise” are not equivalent with closed language terms such as “is” or “are.”

Second Claim Objection

Presently pending claim 36 was objected to under 37 C.F.R. §1.75(c) as allegedly being a duplicate of claim 31. This objection is traversed.

37 C.F.R. §1.75(c) states the following:

“Claims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim.”

Presently pending claim 31 depends from claim 27, and thus shall be construed to include all the elements of claim 27 which is incorporated by reference into claim 31. Presently pending claim 27 depends from claim 26, and thus shall be construed to include all the elements of claim 26 which is incorporated by reference into claim 27. Presently pending claim 26 depends from claim 25, and thus shall be construed to include all the elements of claim 25 which is incorporated by reference into claim 26.

Presently pending claim 25 requires that the colloid be at least partially hydrated with an aqueous medium comprising an active agent. Hence, pursuant to 37 C.F.R. §1.75(c), claim 31 also requires that the colloid be at least partially hydrated with an aqueous medium comprising an active agent.

In contrast, presently pending claim 36 does not require that the colloid be at least partially hydrated with an aqueous medium comprising an active agent.

Therefore, it follows that claim 36 is **not** a duplicate of claim 31. Withdrawal of this objection is respectfully requested.

First Rejection Under 35 U.S.C. §103

Claims 1, 19, 21, 24, 29, and 34 were rejected under 35 U.S.C. §103(a) as allegedly obvious over US 4,482,386 [“Wittwer”]. This rejection is traversed.

It is well established that a *prima facie* case of obviousness requires, among other things, a showing that all claim elements are considered when determining patentability against

the cited references. Applicants submit that Wittwer does not meet this test as applied to the pending claims.

Solution To A Problem – Obvious To Try

The Office Action at page 6, line 8, states that Wittwer is directed to solving the same problem as that of the instantly claimed invention. It appears therefore that the obviousness rejection is based on the “obvious to try” rationale. According to this rationale, it is obvious to choose from a finite number of predictable solutions when solving a recognized problem.

As stated in KSR, "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." KSR at 1397. In order to support a *prima facie* case of obviousness based on this rationale, the Examiner **must** establish the following:

1. That there had been a recognized problem or need in the art including a design need or market pressure to solve a problem;
2. That there had been a finite number of identified predictable potential solutions; and
3. That one of ordinary skill in the art could have pursued the known potential options with a reasonable expectation of success.

Regarding item 1, the Office Action at page 6 states that the recognized problem was to obtain equilibrium swell, avoid rapid degradation, and maintain the water content.

Regarding item 2, the Office Action does not establish that there had been a finite number of identified predictable potential solutions.

To the contrary, at col. 2 lines 49-60, Wittwer states that the hydrophilic polymer may be modified by crosslinking agents such as salts or tri or tetravalent metals, aldehydes, dialdehydes, halogenated aldehydes, mucochloric acid, 1,1- and 1-4 diketones, quinones, acid anhydrides, vinylsulfones, acrylamides, products with 3-membered rings such as ethyleneoxide

or ethyleneimine, carbamoylonium compounds, *etc.*, and that by such crosslinking agents the water-swellability can be varied within wide limits.

Clearly, Wittwer's list of crosslinking agents is admittedly incomplete by use of the term *etcetera*, and thus Wittwer cannot be used to establish that there were a finite number of solutions to obtain the presently claimed equilibrium swells.

Moreover, assuming for the sake of argument that Wittwer did establish a finite number of solutions (which it did not), Wittwer does not establish that such a finite number of solutions were also *identified and predictable* solutions, as required by the "obvious to try" rationale.

Regarding item 3, the Office Action does not establish that one of ordinary skill in the art could have pursued the known potential options with a reasonable expectation of success.

Therefore, for at least the reasons stated above, the current record does not establish a *prima facie* case of obviousness. Withdrawal of this rejection is respectfully requested.

As previously indicated, presently pending independent claim 1 is drawn to an extrudable fragmented biocompatible resorbable single phase aqueous colloid. The single phase aqueous colloid has an equilibrium swell from 400% to 5000%.

In general terms, Wittwer describes varying water-swellability within certain limits at Col. 2, lines 57-60. More specifically, Wittwer describes an absorption isotherm at col. 3, lines 31-46 and at Fig. 1. According to Fig. 1, the water content is within a range from about 0.0 to about 0.5 (kg water per kg gelatin).

As indicated in the instant application at, for example, page 18 lines 17-28, the term "equilibrium swell" can be defined as the percent swell at equilibrium, and the term "percent swell" can be defined as the dry weight subtracted from the wet weight, divided by the dry weight and multiplied by 100.

According to this construction, Wittwer's maximum water content of about 0.5 involves a dry weight of 1.0kg and a wet weight of 1.5kg. Hence, Wittwer's resulting maximum percentage is $((1.5-1)/1)*(100) = \underline{50\%}$. Wittwer's 50% value relates to water content, but Wittwer

does not mention equilibrium swell value ranges at all. In particular, Wittwer does not mention equilibrium swell value ranges such as those presently claimed.

Thus, although Wittwer may discuss water content or varying the water swellability, Wittwer does not teach or suggest equilibrium swells from 400% to 5000% as presently claimed.

Presently pending claims 19, 21, 24, 29 depend from base claim 1, and are therefore allowable as depending from an allowable base claim as well as for the nonobvious combination of elements they recite.

Presently pending independent claim 34 also recites a colloid having a similar equilibrium swell, and for many of the reasons given above with regard to claim 1, is also nonobvious in view of Wittwer.

Second Rejection Under 35 U.S.C. §103

Claims 25-27 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Wittwer in view of US 4,124,705 ["Rothman"] and US 4,515,637 ["Cioca"]. This rejection is traversed.

As noted above, the presently claimed equilibrium swells of base claim 1 is not obvious in view of Wittwer. Rothman discusses a suspension of minute polysaccharide particles, and Cioca discusses a collagen-thrombin hemostatic composition. Yet neither Rothman nor Cioca teach or suggest a single phase aqueous colloid having an equilibrium swell from 400% to 5000%. Hence, these references do not remedy the deficiencies of Wittwer, and the proposed combination does not support a *prima facie* case of obviousness for presently pending claims 25-27, which depend from base claim 1. Withdrawal of this rejection is respectfully requested.

Third Rejection Under 35 U.S.C. §103

Claims 31, 32, 35, and 36 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Wittwer in view of Rothman and US 6,129,761 ["Hubbell"], **OR** Wittwer in view of Hubbell. This rejection is traversed.

As noted above, the equilibrium swells of claims 1, 35, and 36 are not obvious in view of Wittwer, or Wittwer in combination with Rothman. Hubbell describes certain hydrogel compositions, but has not been shown to teach or suggest equilibrium swells from 400% to

5000% as presently claimed, and therefore does not remedy the deficiencies of Wittwer and Rothman. Withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,

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